Fundamental Investigator/Coordinator Orientation

Communication
UMCIRB web site http://www.ecu.edu/irb/
UMCIRB e-mail umcirb@ecu.edu

Required Reading
UMCIRB Standard Operating Practices (SOP) and Policies: http://www.ecu.edu/cs-acad/oric/irb/policies-procedures.cfm
Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Recommended Reading and Resources
OHRP web site: http://www.hhs.gov/ohrp/
Common Rule (45 CFR 46) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
UMCIRB web site www.ecu.edu/irb
Compliance Oversight from OHRP: http://www.hhs.gov/ohrp/compliance/index.html
Policy and Guidance from OHRP: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html
Human Subjects Decision Chart: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html
Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

21 CFR 50 (FDA), Protection of Human Subjects
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=50&showfr=1

21 CFR 56 (FDA), Institutional Review Boards
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=56&showfr=1

FDA IRB Information Sheets
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm

Differences Between DHHS and FDA
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm

Good Clinical Practice
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Required Education
UMCIRB website education for the CITI modules: http://www.ecu.edu/cs-acad/oric/irb/education-modules.cfm

Tools
Informed Consent Checklist http://www.hhs.gov/ohrp/policy/consentckls.html
IRB criteria for review (45 CFR 46.111)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

Categories of review—exempt http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

Categories of review—expedited http://www.hhs.gov/ohrp/policy/expedited98.html

Concepts
Vulnerable populations—minors
Vulnerable populations—prisoners
Conflict of interest for IRB members
Informed consent process
Advertising and recruiting
Privacy and confidentiality
Data monitoring
IRB meeting processes and procedures
Institutional boilerplate language
Review of new studies
Review of requested modifications
Review of revisions
Continuing review
Review of adverse events
Review of protocol deviations
Scope of IRB
Relationship of IRB to the institution
Relationship of IRB to regulatory agencies
Research designs
Office responsibilities
Committee responsibilities
Investigator responsibilities